Amendment No. 1 to SB0205

FILED
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Clerk _____
Comm. Amdt. _____
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Ford
Signature of Sponsor

AMEND Senate Bill No. 205 House Bill No. 62*

by deleting all language after the enacting clause and by substituting instead the following:

SECTION 1. Tennessee Code Annotated, Title 68, is amended by creating a new chapter designated as Chapter 58 relative to medical research involving human subjects, and by inserting Sections 2 and 3 below as new sections thereto.

SECTION 2. Any research involving human subjects that is subject to the federal regulations for the protection of human subjects in research found at 21 C.F.R. 50 et. seq. and that is conducted in this State shall comply with the provisions of this part. Failure to comply with the provisions of this part shall be grounds for discipline under the licensure regulations for any individual health practitioners participating in the research pursuant to Title 63 as well as for the health facility at which the research is conducted pursuant to Title 68, Chapter 11.

SECTION 3. When documenting informed consent in research involving human subjects as required by 21 C.F.R. 50.27, the subject of the research must be given both a written consent document as described in 21 C.F.R. 50.27(b)(1) and an oral presentation of the elements of informed consent as described in 21 C.F.R. 50.27(b)(2). The oral presentation of the elements of informed consent shall comply with all requirements of 21 C.F.R. 50.27(b)(2) including that the subject or the subject's personal representative shall sign and be given a copy of the written consent document described in 21 C.F.R. 50.27(b)(1) rather than the short form consent document allowed by 21 C.F.R. 50.27(b)(2). The oral presentation must be given by a person knowledgeable about the details and risks of the research. When a witness is required according C.F.R. 50.27(b)(2), or when requested by a potential research participant, such witness must be present not only during the signing of the consent but during the entire oral presentation. The witness to the consent must be a non-biased third party as defined as

someone who is not in a direct or indirect reporting relationship to the individuals conducting the research and is not affiliated with the research study. All other requirements of 21 C.F.R. 50.27(b)(2) must be met in addition to the requirements specified in this section.

SECTION 4. This act shall take effect July 1, 2005, the public welfare requiring it.